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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/237,183 | 01/26/1999 | NORDINE CHEIKH | 04983.0015.U | 9529 |

22930 7590 01/29/2002

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EXAMINER

MARSCHER, ARDIN H

ART UNIT PAPER NUMBER

1631

DATE MAILED: 01/29/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/237,183

Applicant(s)

Chelkh et al.

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Nov 14, 2001

2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1035 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1, 2, and 7-17 is/are pending in the application

~~4a) Of the above, claim(s) 3-6 have been canceled. is/are withdrawn from consideration~~

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1, 2, and 7-17 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1, 2, and 7-17 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

20) ☐ Other: _____

Applicants' arguments, filed 11/14/01, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have further argued the restriction requirement but without adding any further specific reasons in support thereof. The traversal argument is thus still deemed non-persuasive and the FINALITY of the restriction requirement is maintained.

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context

of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 1, 2, and 7-17 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by either specific and/or substantial utility or a well established utility.

This rejection is maintained and reiterated from the previous office action, mailed 8/15/01, and as necessitated by amendment regarding newly added claims 7-17. Applicants argue firstly that sequence identity comparisons supply evidence of

enzymatic activity of the encoded polypeptides of the instant invention. The following new grounds regarding the lack of substantial utility for the use of sequence identity or comparisons for protein and/or gene activity determination is added as follows.

It is noted that applicants have listed a sequence which is known in the prior art and which has a high percentage sequence similarity to a claimed sequence. Absent factual evidence, a percentage sequence similarity of less than 100 % is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. It is known for nucleic acids as well as proteins, for example, that even a single nucléotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility and/or enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to

be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Gerhold et al. [BioEssays, Volume 18, Number 12, pages 973-981{1996}]; Wells et al. [Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550 (1997)]; Russell et al. [Journal of Molecular Biology, Volume 244, pages 332-350 (1994)]; and Attwood [Science, Vol. 290, No. 5491, pages 471-473 (2000)].

Applicants further argue that asserted utility must be accepted unless sound reasoning or evidence rebuts the assertion. The above paragraph is deemed sound reasoning and evidence to rebut the assertion of enzymatic activity as being determinable via sequence homology of identity. Thus, the rejection is maintained but additionally supported as noted above.

Claims 1, 2, and 7-17 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention. This rejection is reiterated and maintained from the previous office action, mailed 8/15/01, and as necessitated by amendment regarding newly added claims 7-17. The arguments regarding this rejection have already been responded to

regarding the above lack of utility rejection as being equally non-persuasive for the same reasons as given above.

Claims 1, 2, and 7-17 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This lack of written description rejection is maintained and reiterated from the previous office action, mailed 8/15/01, and as necessitated by amendment regarding newly added claims 7-17. Applicants argue that the disclosure of all things encompassed by the claims do not need to be disclosed. This is acknowledged, however, specific embodiments of the claims are directed to the encoding sequence for various enzymes. These enzyme coding regions lack written description in that only fragments thereof are disclosed. These enzyme coding regions are clearly intended to be instant claim embodiments as listed, for example, in claims 1 and 2 via their enzyme names. Applicants have not argued what written description is instantly present for these full enzyme coding region embodiments. Applicants, however, have argued that they have supplied structural information regarding their invention in the form of specific sequences. In response it has been stated that these sequences do, in fact, have written

description. The issue is that the entire enzyme coding region does not. Applicants have not supplied any structural information that extends the sequences in the claims to these full enzyme coding regions thus still supporting this rejection.

The disclosure is objected to because it contains an embedded hyperlink and/or other form or browser-executable code. Applicants are required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. Such code is present in the specification at page 19, lines 10-17, and elsewhere. It is noted that applicants have reduced the code but, unfortunately not enough. An attempt to utilize the remaining hyperlinks by the Examiner's computer resulted in these hyperlinks still being usable and interpretable as such. Therefore, further deletion is required in order to satisfy this correction requirement. Appropriate correction is required.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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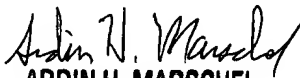
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

January 25, 2002


ARDIN H. MARSCHEL
PRIMARY EXAMINER